

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Abraham J. Domb

Serial No.:

10/763,876

Art Unit:

Not Yet Assigned

Filed:

January 23, 2004

Examiner:

Not Yet Assigned

For:

POLYMERIC FORMULATIONS FOR DRUG DELIVERY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including three (3) pages of Form PTO-1449. Most of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/433,143, filed May 30, 2003, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

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INFORMATION DISCLOSURE STATEMENT

U.S. Patents

Number	Issue Date	<u>Patentee</u>	Class/Subclass
4,999,417	03-12-1991	Domb	528/271
5,171,812	12-15-1992	Domb	526/318.2
5,179,189	01-12-1993	Domb, et al.	528/271

Foreign Documents

Number	Publication Date	<u>Patentee</u>	Country
0 598 131	05-25-1994	Kansai Paint Co., Ltd.	EP
WO 93/05096	03-18-1993	Nova Pharm Corp.	PCT
WO 96/22270	07-25-1996	Yissum Res. Dev. Co.	PCT

Publications

BREMER & OSMUNDSEN, "Fatty acid oxidation and its regulation," in <u>Fatty Acid Metabolism and Its Regulation</u> (Numa, ed.) Elsevier: New York, p. 113-154 (1984).

DANG, et al., "Effects of GLIADEL wafer initial molecular weight on the erosion of wafer and release of BCNU," J. Control. Rel. 42: 83-92 (1996).

DOMB & LANGER, "Polyanhydrides. I. Preparation of high molecular weight polyanhydrides," *J. Polym. Chem.* 25: 3373-3386 (1987).

DOMB & MANIAR, "Absorbable biopolymers derived from dimer fatty acids," J. Polym. Sci. Polymer Chem. 31: 1275-1285 (1993).

DOMB, et al., "Poly(anhydrides). 3. Poly(anhydrides) based on aliphatic-aromatic diacids," *Macromolecules* 22: 3200 (1989).

DOMB, et al., "Polyanhydrides" in <u>Handbook of Biodegradable Polymers</u> (Domb, et al., eds.) Hardwood Academic Publishers, p. 135-159 (1997).

DOMB, et al., "Polyanhydrides as carriers of drugs" in <u>Biomedical Polymers: Designed-to-Degrade Systems</u> (Shalaby, ed.) Hanser Publishers: Munich, p. 69-96 (1994).

GOPFERICH, in <u>Handbook of Biodegradable Polymers</u> (Domb, et al., eds.) Hardwood Academic Publishers, p. 451-471 (1997).

HELLER, "Biodegradable polymers in controlled drug delivery," CRS Crit. Rev. Ther. Drug Carrier Syst. 1: 39-90 (1984).

U.S.S.N.: 10/763,876 Filed: January 23, 2004

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HOPFENBERG, "Controlled release from erodible slabs, cylinders, and spheres" in Controlled Release Polymeric Formulations (Paul, et al., eds.) ACS Symposium Series, Washington DC, 33: 26-32 (1976).

LEONG, et al., "Polyanhydrides for controlled release of bioactive agents," *Biomaterials* 7: 364-371 (1986).

MÄDER, et al., "In vitro/in vivo comparison of drug release and polymer erosion from biodegradable P(FAD-SA) polyanhydrides – a noninvasive approach by the combined use of electron paramagnetic resonance spectroscopy and nuclear magnetic resonance imaging," *Pharm. Res.* 14(6): 820 (1997).

PARK, et al., "Biodegradable polyanhydride devices of cefazolin sodium, bupivacaine, and taxol for local drug delivery: preparation, and kinetics and mechanism of in vitro release," *J. Control. Rel.* 52: 179-189 (1998).

ROSEN, et al., "Bioerodible polyanhydrides for controlled drug delivery," *Biomaterials* 4: 131-133 (1983).

TEOMIM, et al., "Perivascular delivery of heparin for the reduction of smooth muscle cell proliferation after endothelial injury," *J. Control Rel.* 60: 129-142 (1999).

TEOMIM, et al., "Ricinoleic acid-based biopolymers," J. Biomed. Mater. Res. 45: 258-287 (1999).

TEOMIM, et al., "Fatty acid terminated polyanhydrides," J. Polym. Sci. 37: 3337-3344 (1999).

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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patred L. Pabst

Reg. No. 31,284

Dated: April 8, 2004

HOLLAND & KNIGHT LLP One Atlantic Center 1201 West Peachtree Street, N.E. Suite 2000 Atlanta, Georgia 30309-3400 404-817-8473 FAX 404-817-8588 www.hklaw.com U.S.S.N.:

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Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date:

April 8, 2004

Erica C. Boughner

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Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE TO STATEMENT BY APPLICANT (See as many sheets as necessary)	Application Number	10/763,876	
13 E	Filing Date	January 23, 2004	
<i>b</i> 1	First Named Inventor	Abraham J. Domb	
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Catellia A Land	Examiner Name		
neet 1 of 3	Attorney Docket Number	PG 102	

U.S. PATENT DOCUMENTS									
Examiner Cite Initials* No.1						US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)							
		4,999,417	Domb	03-12-1991					
		5,171,812	Domb	12-15-1992					
		5,179,189	Domb, et al.	01-12-1993					
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-			F	OREIGN PATENT DOCUMENT	rs		
 Cite No. ¹		Foreign Patent Docur	nent	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	Office.3	Number ⁴	Kind Code⁵ (if known)		·		
	EP	0 598 131		Kansai Paint Co., Ltd.	05-25-1994		I
	PCT	WO 93/05096		Nova Pharm Corp.	03-18-1993		
	PCT	WO 96/22270		Yissum Res. Dev. Co.	07-25-1996		ļ
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¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant to place a check mark here if English language Translation is attached.

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				Group Art Unit	
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	PG 102

	OTHER ART NON PATENT LITERATURE DOCUMENTS	
Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
·	BREMER & OSMUNDSEN, "Fatty acid oxidation and its regulation," in <u>Fatty Acid Metabolism and Its Regulation</u> (Numa, ed.) Elsevier: New York, p. 113-154 (1984).	
	DANG, et al., "Effects of GLIADEL wafer initial molecular weight on the erosion of wafer and release of BCNU," J. Control. Rel. 42: 83-92 (1996).	
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				Examiner Name	
Sheet	3	of	3	Attorney Docket Number	PG 102

	0	OTHER ART NON PATENT LITERATURE DOCUMENTS	T²
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	,
		LEONG, et al., "Polyanhydrides for controlled release of bioactive agents," <i>Biomaterials</i> 7: 364-371 (1986).	
		MÄDER, et al., "In vitro/in vivo comparison of drug release and polymer erosion from biodegradable P(FAD-SA) polyanhydrides — a noninvasive approach by the combined use of electron paramagnetic resonance spectroscopy and nuclear magnetic resonance imaging," <i>Pharm. Res.</i> 14(6): 820 (1997).	
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		TEOMIM, et al., "Perivascular delivery of heparin for the reduction of smooth muscle cell proliferation after endothelial injury," J. Control Rel. 60: 129-142 (1999).	
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